

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 02/09/94 OUT 03/02/94

Reviewed by Srinivas Gowda Date 03/02/94

EPA Reg. No. or File Symbol 1043-92

EPA Petition or EUP No. None

Date Division Received 12-22-93

Type Product Hospital Disinfectant

MRID No (s) 430618-01 to 430618-03

Product Manager PM 32 (Douglas)

Product Name LpH<sub>2</sub>

Company Name Calgon Vestal Laboratories

Submission Purpose Resubmission in response to Agency letter  
dated Nov. 18, 1993 with additional data  
against Pseudomonas aeruginosa to refute the  
previously submitted failed data (MRID No.  
427594-01) filed under 6(a)(2) and reinstate  
hospital disinfectant claim

Type Formulation Liquid

Active Ingredient (s): %

o-phenylphenol.....7.3

p-tertiary amylphenol.....7.4

200.0      **Introduction:**

200.1      **Uses(s)**

See attached latest accepted label dated 02-06-92.

200.2      **Background Information:**

The submission received 12-22-93, is in response to agency letter dated Nov. 18, 1993 with additional AOAC Use-Dilution Test data on Pseudomonas aeruginosa to refute previously submitted failed data (MRID No. 427594-01) filed under 6(a)(2) and to reinstate hospital disinfection claim.

201.0      **Data Summary**

201.2      **Brief Description of Test:**

Biological Report of Analysis/AOAC Use Dilution Test Data by Florida Department of Agriculture, 3125 Conner Boulevard, MC-1, Tallahassee, Florida 32399-1650, dated 06-03-91 (MRID No. 430618-01).

Biological Report of Analysis/AOAC Use Dilution Test Data by Florida Department of Agriculture, 3125 Conner Boulevard, MC-1, Tallahassee, Florida 32399-1650, dated 02-19-90 (MRID No. 430618-02).

"AOAC Use-Dilution Test for Determining the Efficacy of Calgon Vestal Laboratories LpH<sub>2</sub> Disinfectant Against Pseudomonas aeruginosa ATCC 15442" by Larry N. Wilson and William J. Suling, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated 06-18-93 (MRID No. 430618-03).

201.2      **Conclusions:**

See 202.0



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EFFICACY REVIEW - II

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Date Division Received 12-22-93

Type Product Hospital Disinfectant

MRID No (s) 430618-01 to 430618-03

Product Manager PM 32 (Douglas)

Product Name LpH<sub>sp</sub>

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202.0      **Recommendations**

202.2      **Efficacy Supported by the Data:**

The submitted data by the AOAC Use Dilution Test Method are acceptable to support effectiveness of the product as a hospital disinfectant against Pseudomonas aeruginosa at a 1:256 dilution in the presence of 5% blood serum and 400 ppm CaCO<sub>3</sub> hard water for a contact time of 10 minutes at 20°C.

203.0      **Labeling:**

No labeling was provided.

204.0      **Note to PM 32:**

EETMS recommends PM 32 to reinstate the hospital disinfection claim for this product at this time because the currently submitted data refutes the previously submitted failed data filed under 6(a)(2). This product will be retested by the EMSL in the very near future and if found ineffective registrant will be asked to delete the claims against Pseudomonas aeruginosa.